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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,164	04/01/2004	Esther Regina de Rooij	2183-6412US	1592
24247	7590	05/23/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/817,164	<b>Applicant(s)</b> DE ROOIJ ET AL.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-4,6,7,9,10,14,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-4,6,7,9,10,14,16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/4/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendment filed April 24, 2006 is acknowledged and entered. Claims 2-4, 6, 7, 9, 10, 14, 16 and 17 are pending and under examination.

The rejection of claims 2-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is moot with respect to the cancelled claims, and withdrawn with respect to the pending claims, now amended.

The rejection of claims 2-17 and 19-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is moot with respect to the cancelled claims, and withdrawn with respect to the pending claims, now specifying filter paper.

### ***Information Disclosure Statement***

2. The information disclosure statement filed May 4, 2006 has been considered. A copy of the PTO-1449 is attached to this Office action. The newly filed references after the first Office action prompted the new ground(s) of rejection presented in this Office action. Accordingly, this Office action is made final.

### ***Claim Rejections - 35 USC § 112***

3. (*New Rejection*) Claims 9, 10, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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- Claims 9 and 10 recite the limitation "the representative part of the solid carrier" and "the representative part of the filter paper" in claims 2 and 6, respectively. There is insufficient antecedent basis for these limitations in the claims.
- Claim 9 recites, "wherein the representative part of the solid carrier comprises the whole of the filter paper". This is unclear because the claims from which claim 9 depends, claim 2, requires that the at least one spot of sample is excised from the surrounding filter paper. Correction is required.
- Claims 16 and 17 recite the limitation "the viral RNA" in claim 14. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

4. (New Rejection) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 6, 7, 9, 10, 14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cassol *et al.* (*Mem. Inst. Oswaldo Cruz*, Rio de Janeiro, 1996, 91(3):351-358, "Cassol"). The claims are drawn to a process for preparing at least one sample for a method of detecting and quantifying a nucleic acid of interest in the at least one sample, said process comprising:

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a) administering at least 100 microliters of the at least one sample to a piece of filter paper capable of absorbing the at least one sample, wherein the absorption results in a at least one spot of the at least one sample of the filter paper,

b) drying the filter paper having the absorbed at least one spot of the at least one sample,

c) excising the at least one spot of the at least one sample from the surrounding filter paper,

d) extracting nucleic acid from the at least one spot of the at least one sample with a nucleic acid isolation solution,

e) detecting nucleic acid of interest, if present, and

f) quantifying the nucleic acid of interest in the at least one sample.

In some embodiments, at least 200 or at least 250 microliters of sample is administered to the filter paper. In other embodiments, at least two samples are administered to the filter paper.

Specifically, a known amount of a reference nucleic acid is administered to the filter paper. The nucleic acid of interest is from a virus, specifically, HIV or HTLV, and more specifically, HIV-1.

*[Note that claims 9 and 10 are not included in this rejection because they are indefinite.*

*However, if the claims are amended to render them definite, their subject matter may be included in this rejection later in prosecution.]*

Cassol's disclosure is related to dried blood spots collected on filter paper, used for diagnosis and genetic characterization of HIV-1 (abstract). A method for the direct automated sequencing of HIV-1 field isolates from dried blood collected on filter paper is described on pages 355-356. The method includes the collection of blood by venipuncture and application of approximately 2 milliliters (2000 microliters) to filter paper via drops. The filter paper is air

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dried for three hours and placed in individual envelopes for storage/shipment. When the dried blood spots are analyzed, the spots are excised and subjected to PCR analysis. Figure 1 shows the semi-quantitative detection of HIV-1 drug-resistance mutations by automated sequences of dried blood spot specimens using the above-described analysis. Therefore, the teachings of Cassol anticipate Applicant's claimed invention.

### *Conclusion*

5. No claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on May 4, 2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

*Stacy B. Chen 5/16/2006*

Stacy B. Chen  
Primary Examiner  
May 16, 2006